



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/823,814

04/14/2004

Tsutomu Okada

17614

5629

23389 7590 01/28/2010
SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER

HUPCZEY, JR, RONALD JAMES

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

01/28/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,814	Applicant(s) OKADA, TSUTOMU	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-10 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-10 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments and arguments, received on October 9th, 2009, have been fully considered by the examiner. Currently, claims 1, 7-10 and 14-17 are pending with claim 1 currently amended and claims 14-17 newly added. The following is a complete response to the October 9th, 2009 communication.

Claim Objections

2. Claim 14 is objected to because of the following informalities: Line 2 of claim 14 currently recites "... is set to a dimension such that is cannot be penetrated...". It is the Examiner's suggestion that Applicant change the second "is" to "it" in order to correct the grammatical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 16, the claim currently recites "the distal end portion comprises a triangular plate arranged perpendicular to the axis". Applicant's attention is first directed to the rejection below of the claim under 35 U.S.C. 112, 2nd paragraph for being unclear as to the structural relationship of the plate to the remainder of the device. It is the Examiner's position

Art Unit: 3739

that while the subject matter in claim 16 is supported in figures 8A and 8B as well as page 21, line 25 - page 23, line 13 of the specification, the embodiment which claim 1 (the parent of claim 16) is directed to is never adequately disclosed or described as containing a triangular plate on the distal end portion of the electrode portion. From the Examiner's best understanding of the specification, claim 1 is directed towards the embodiment depicted in figures 7A-7B. In figures 7A-7B, the electrode portion is shown with a hooked/bent distal end portion and the openings are shown as extending outwardly from the slide hole in a straight fashion. In contrast, the embodiment shown in figures 8A-8B display openings with a generally triangular shape. As such, it is the Examiner's position that the specification fails to adequately set forth support for a radio knife containing both a plurality of straight openings outwardly extending from the slide hole further comprising a triangular arranged on the distal end portion of the electrode portion. Appropriate correction is required.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 16, the claim currently recites the limitation of "wherein the distal end portion comprises a triangular plate arranged perpendicular to the axis". This recitation is unclear and confusing for a number of reasons, rendering the scope of the claim unascertainable. Specifically, the recitation of "the distal end portion" in the claim is not related to any other portion of the device. In parent claim 1, both the flexible sheath and the electrode portion are

Art Unit: 3739

described as having a "distal end portion" and as such, it is unclear which of the flexible sheath and the electrode portion the triangular portion is located on. Additionally, Applicant's recitation of "perpendicular to the axis" is unclear. While Applicant has adequately set forth the sheath having an axis, the orientation of the axis (i.e. longitudinal, running from the proximal end portion to the distal end portion of the flexible sheath) is unclear and as such, the orientation of the "triangular plate arranged perpendicular to the axis" to the remainder of the device is unclear. For the purpose of examination, the Examiner will be taken the triangular plate to be located on the distal end portion of the electrode portion and arranged perpendicular to the longitudinal axis as can be seen in Applicant's figure 4.

Claim Rejections - 35 USC § 103

7. Claims 1 and 7-9, 14-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokai (Pub. No. 4-329944) in view of Rexroth et al (hereinafter "Rexroth")(US Pat. No. 4,943,290).

Regarding claim 1, Kokai discloses a radio knife (electrosurgical device **1**) containing an electrically insulating sheath (insulating flexible tube **2**) having one flow channel inside (see channel in Figure 1), a distal end portion and a proximal end portion, the distal end portion of the sheath having a distal opening (tip opening **13**) and an axis, a support member (stopper member **4**) which closes the distal opening of the sheath (see Figure 4), the support member having a slide hole with a diameter smaller than that of the distal opening extending along the axis thereof (see Figures 1 and 4); an operating wire (operation wire **14**) axially moveable in the sheath (see paragraph [0013], lines 4-6), the rod-shaped portion being passed through the slide hole for axial projection and retraction (movement represented by **X**, see Figure 5); a control section (operation

Art Unit: 3739

part **3**, operation handle **15**) which is provided on the proximal end portion of the sheath (see Figure 5) and controls the operating wire to project and retract the electrode portion in the axial direction (see paragraph [0013], lines 8-14), the control section having a high-frequency current supply portion (see paragraph [0010], lines 6-8) which supplies high-frequency current to the electrode portion (see paragraph [0011], lines 9-12), a liquid feed portion (cock **17**) which is provided on the proximal end side of the sheath and feeds liquid through the one flow channel inside the sheath towards the distal opening (see paragraph [0014]) and an opening for liquid feed which is formed in the support member, the opening being arranged around the slide hole (see paragraph [0014], line 3-5), communicating to the one flow channel (see Figure 1 and paragraph [0014]) and partially blocking flow in the vicinity of the distal end portion (see Figure 1). Kokai fails to disclose the inclusion of a plurality of openings extending outward from the slide hole with an inner portion of each of the straight openings being coupled to the slide hole and is silent in regard to the conductivity properties of the support member.

Rexroth discloses an electrosurgical device (electrosurgical apparatus **10**) containing an electrically insulating sheath (duct means **70**, see col. 9; 3-5) having a distal end portion and proximal end portion, the distal end portion of the sheath having a distal opening and an axis (see Figure 4). Rexroth further discloses the insulation sheath to inherently form a support member which closes the distal opening of the sheath and is insulating. The insulating tip defines a slide hole for the rod-shaped electrode shaft (electrode shaft **50**), the slide hole having a diameter smaller than that of the distal opening (see Figure 14). Additionally, Rexroth discloses the device to have a liquid feed portion (input fluid port **18**) and a plurality of straight openings (see openings of channels **75-78** extending in a straight manner into the duct means **70**, Figure 6) for

Art Unit: 3739

liquid feed (see col. 8; 62 – col. 9; 8) extending outward from the slide hole (opening as in figure 6 extending from electrode shaft **50** outwardly to the inner portion of the means **70**) wherein an inner portion of each of the straight openings is coupled to the slide hole (portion of each of openings of channels **75-78** coupled to electrode shaft **50**) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a plurality of openings such as those disclosed by Rexroth in conjunction with the device disclosed by Kokai to provide an electrosurgical device with a plurality of straight openings extending outwardly from and coupled to the slide hole. As disclosed by Rexroth, it is old and well known to provide a plurality of openings for liquid to flow from in order to create a superior flow pattern to the proximity of the electrode tip. Furthermore, it would have been obvious to provide for an electrically insulative support member as discloses by Rexroth to the device of Kokai to prevent the short circuiting of the device.

Regarding claims 7 and 15, Kokai discloses the sheath to have an extending portion extending ahead of the support member wherein the extending portion has an internal space which stores the electrode portion (see Figure 5).

Regarding claims 8 and 9, Kokai fails to disclose an extending portion location on the distal end portion of the rod-shaped portion and extending across the extending direction of the rod-shaped portion and for the extending portion to be a hooked bent portion extending substantially at right angles to the distal end portion. Rexroth discloses the electrode portion (electrode shaft **50**) to contain an extending portion (ball tip **26**) located on the distal end portion of the rod-shaped portion and extending across the extending direction of the rod-shaped portion (see Figure 15). Rexroth further discloses the extending portion to be a hooked bent portion

Art Unit: 3739

(electrode tip **26C**) extending at substantially right angles to the distal end portion (see Figure 18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Kokai with the electrode tip designs disclosed by Rexroth in order to catch tissue around the extending portion.

Regarding claim 14, Kokai fails to disclose the plurality of straight openings as noted in the rejection of claim 1 above. Rexroth discloses the plurality of straight openings (see openings of channels **75-78** in figure 6) and further discloses that the openings are set to a dimension such that each cannot be penetrated by the electrode portion (support walls **80-83** converging to define the openings with channels **75-78** and dimensioned such that electrode shaft **50** cannot penetrate into the opening, see structural relationship in figure 6).

Regarding claim 17, Kokai discloses a radio knife (electrosurgical device **1**) containing an electrically insulating sheath (insulating flexible tube **2**) having one flow channel inside (see channel in Figure 1), a distal end portion and a proximal end portion, the distal end portion of the sheath having a distal opening (tip opening **13**) and an axis, a support member (stopper member **4**) which closes the distal opening of the sheath (see Figure 4), the support member having a slide hole with a diameter smaller than that of the distal opening extending along the axis thereof (see Figures 1 and 4); an operating wire (operation wire **14**) axially moveable in the sheath (see paragraph [0013], lines 4-6), the rod-shaped portion being passed through the slide hole for axial projection and retraction (movement represented by **X**, see Figure 5); a control section (operation part **3**, operation handle **15**) which is provided on the proximal end portion of the sheath (see Figure 5) and controls the operating wire to project and retract the electrode portion in the axial direction (see paragraph [0013], lines 8-14), the control section having a high-frequency current

Art Unit: 3739

supply portion (see paragraph [0010], lines 6-8) which supplies high-frequency current to the electrode portion (see paragraph [0011], lines 9-12), a liquid feed portion (cock **17**) which is provided on the proximal end side of the sheath and feeds liquid through the one flow channel inside the sheath towards the distal opening (see paragraph [0014]) and an opening for liquid feed which is formed in the support member, the opening being arranged around the slide hole (see paragraph [0014], line 3-5), communicating to the one flow channel (see Figure 1 and paragraph [0014]) and partially blocking flow in the vicinity of the distal end portion (see Figure 1). Kokai fails to disclose the inclusion of a plurality of triangular openings extending outwards from the slide hole with an inner end portion of each of the triangular openings being coupled to the slide hole and is silent in regard to the conductivity properties of the support member.

Rexroth discloses an electrosurgical device (electrosurgical apparatus **10**) containing an electrically insulating sheath (duct means **70**, see col. 9; 3-5) having a distal end portion and proximal end portion, the distal end portion of the sheath having a distal opening and an axis (see Figure 4). Rexroth further discloses the insulation sheath to inherently form a support member which closes the distal opening of the sheath and is insulating. The insulating tip defines a slide hole for the rod-shaped electrode shaft (electrode shaft **50**), the slide hole having a diameter smaller than that of the distal opening (see Figure 14). Additionally, Rexroth discloses the device to have a liquid feed portion (input fluid port **18**) and a plurality of triangular openings (see openings of channels **75-78** having a triangular shape similar to shapes depicted in Applicant's figures 8A and 8B, Figure 6) for liquid feed (see col. 8; 62 – col. 9; 8) extending outward from the slide hole (opening as in figure 6 extending from electrode shaft **50** outwardly to the inner portion of the means **70**) wherein an inner portion of each of the straight openings is coupled to

Art Unit: 3739

the slide hole (portion of each of openings of channels **75-78** coupled to electrode shaft **50**)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a plurality of openings such as those disclosed by Rexroth in conjunction with the device disclosed by Kokai to provide an electrosurgical device with a plurality of straight openings extending outwardly from and coupled to the slide hole. As disclosed by Rexroth, it is old and well known to provide a plurality of openings for liquid to flow from in order to create a superior flow pattern to the proximity of the electrode tip. Furthermore, it would have been obvious to provide for an electrically insulative support member as discloses by Rexroth to the device of Kokai to prevent the short circuiting of the device.

8. Claims 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokai (Pub. No. 4-329944) in view of Rexroth et al (US Pat. No. 4,943,290) as applied to claim 8 above, and further in view of Kittur et al (US Pat. No. 5,846,241).

Both Kokai and Rexroth fail to disclose the inclusion of a plate-like electrode at the distal end portion. Kittur et al discloses a radio knife (electrocautery device **10**) containing an extending portion (moveable head **22**) in a plate-like arrangement (second electrode **24**) coupled to the distal end of the rod-shaped portion (second wire **20**). Kittur further displays the portion to have a triangular shape (see shape of moveable head **22** in figure 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a plate-like electrode as disclosed by Kittur et al to the joint device of Kokai and Rexroth. All three device disclosed are directed toward the same field of endeavor and the utilization of a triangular plate-like electrode would increase the versatility of the device, effectively allowing it to successfully perform a wider variety of treatments.

Response to Arguments

9. Applicant's arguments filed October 9th, 2009 have been fully considered but they are not persuasive.

10. In response to Applicant's argument that the combination of Kokai and Rexroth fail to teach each of the limitations of instant claim 1, the Examiner respectfully disagrees. While Applicant has argued on page 7 of the Remarks that the arrangement of the electrode of Rexroth ***may become detached from the support walls and displaced about the center*** if the supports walls were worn due to insertion and/or retraction of the electrode rod, such an argument of what ***may occur*** is not seen by the Examiner as a clear argument regarding the structural/functional differences between the instant device and the prior art of record. In response, the Examiner proffers that if wear would occur in the instant invention, the electrode could wear down the circular walls of the slide hole, enlarge the entrance to one of the channels **33** such that the electrode would then be displaced off center due to the wear. Furthermore, it is noted that the features upon which applicant relies (i.e., the device's ability to keep the electrode centered within the slide hole and the device's ability to not be subject to wear over multiple extension/retraction cycles) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Lastly, in light of Applicant's amendment to claim 1 and addition of new claims 14-17, it is the Examiner's position that the new interpretations proffered in the rejection above under Kokai in view of Rexroth and Kokai and Rexroth in view of Kittur still anticipate and/or fairly suggest each of the limitations presented.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH